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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Justin Thibodeau, Plaintiff, v. Cochlear Limited, et al., Defendants.	No. CV-13-02184-PHX-DGC **ORDER**

Defendants Cochlear Limited and Cochlear Americas Corporation have filed motions to dismiss under Rule 12(b)(6). Docs. 26, 27. The motions are fully briefed and no party has requested oral argument. The Court will grant the motions with respect to all claims other than Defendants' alleged failure to warn the FDA.

I. Background.

Cochlear Limited ("CLTD") is an Australian public company. Doc. 26 at 3. Cochlear Americas Corporation ("CAM") is a Delaware corporation and a subsidiary of CLTD that distributes CLTD products in the United States. *Id.* CLTD is the manufacturer of the Nucleus CI512 cochlear implant device which "electrically stimulates nerves inside the ear through an implanted electrode, thereby restoring a sense of hearing to those with severe to profound nerve deafness." *Id.* at 1-2. The CI512 is a Class III medical device, approved by the Food and Drug Administration ("FDA") pursuant to its premarket approval process ("PMA"). *Id.*

Plaintiff Justin Thibodeau alleges that he was implanted with a CI512 device at Banner Desert Medical Center in Mesa, Arizona, in July 2011. *Id.* at 6. Plaintiff claims

that his implant "failed due to an electronic failure caused by a loss of hermeticity (i.e. failure of the moisture impervious seal)[.]" Doc. 1, ¶ 81. Plaintiff alleges that the loss of hermeticity was caused by "unintended variations in the brazing process that occurred during Defendants' manufacture" of the implant. Id. ¶ 82. "Brazing is the process that joined the feed through of Plaintiff's [implant] to its titanium chassis." Id. ¶ 83. Plaintiff alleges that "microcracks" in the braze joints of his implant allowed water molecules to enter the implant and "cause the malfunction and eventual failure of the [implant]'s electronic components." Id. ¶ 86.

The CI512 was part of a voluntary recall initiated by CAM in September 2011. *Id.* ¶ 70. The FDA then issued a "Class 2 Recall" of all unimplanted CI512 devices on October 3, 2011. *Id.* ¶ 71. Plaintiff alleges that Defendants publicly released two letters from the CEO of CLTD which stated that "unexpected variations in the brazing process during manufacturing" led to a loss of hermeticity. *Id.* ¶¶ 74, 75.

Plaintiff asserts claims for defective manufacturing, defective design, failure to warn, negligence, negligence per se, breach of express warranty, breach of implied warranty of merchantability and fitness for a particular purpose, and negligent misrepresentation. *Id.* ¶¶ 116-77.

II. Legal Framework.

Defendants argue that Plaintiff's claims are preempted by the Medical Devices Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). Doc. 26 at 7. Relying on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), Defendants argue that "state law product liability claims such as those alleged by Plaintiff in this case fall squarely within the preemption provision of the [MDA]." Doc. 26 at 2.

In recent years, many cases across the country have considered both the express and implied preemption of claims under the MDA. Several courts have thoroughly and ably summarized the legal background. *See, e.g., Scovil v. Medtronic, Inc.*, -- F. Supp. 2d --, 2014 WL 502923, at *4-8 (D. Ariz., Feb. 7, 2014); *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-0049AWISKO, 2014 WL 346622, at *3-5 (E.D. Cal., Jan. 30, 2014);

Kashani-Matts v. Medtronic, Inc., No. SACV 13-01161-CJC (RNBx), 2013 WL 6147032, at *3 (C.D. Cal., Nov. 22, 2013); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1173-76 (C.D. Cal. 2013); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 985-87 (D. Ariz. 2013).

Section 360k of the MDA includes this preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

The Supreme Court has considered § 360k and preemption in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and *Riegel*. In *Lohr*, the Supreme Court held that state-law claims that "parallel" federal requirements are not preempted by § 360k. 518 U.S. at 495-96.

In Buckman, the court held that claims that a device manufacturer had made fraudulent representations to the FDA were "inherently federal in nature" because the relationship between the manufacturer and the FDA "originates from, is governed by, and terminates according to federal law." 531 U.S. at 347-48. The court held that such "fraud-on-the-FDA" claims were impliedly preempted. *Id.* at 348.

Riegel is the Supreme Court's most recent consideration of the MDA's preemption provision. 552 U.S. at 315. The medical device at issue in *Riegel* was a balloon catheter, which was used during the plaintiff's heart surgery in a manner inconsistent with its FDA-approved labeling. *Id.* at 320. In discussing the rigor of the PMA process, the court noted that the FDA "spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness[.]'" *Id.* at 318 (citing § 360e(d)). The court noted that

the FDA "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* The court used a two-part test to determine whether state law claims are preempted under § 360k: courts must determine (1) whether the federal government established "requirements" applicable to the device in question, and, if so, (2) whether the state common law claims are based on state law requirements "that are different from, or in addition to the federal ones" and "relate to safety and effectiveness." *Id*. at 321-22 (citing § 360k(a)).

Riegel found that the PMA imposes "requirements" applicable to each specific device and that "common-law causes of action for negligence and strict liability do impose 'requirements' and would be preempted by federal requirements specific to a medical device." *Id.* at 323-24. *Riegel* affirmed the earlier holding in *Lohr* that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330. The Ninth Circuit has considered § 360k twice since *Riegel* and has confirmed that "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013) (quoting *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc), *cert. denied by Medtronic Inc. v. Stengel*, -- S. Ct. --, 2014 WL 2807193 (June 23, 2014)).

III. Analysis.

Plaintiff does not dispute Defendants' reading of *Riegel* or the subsequently issued Ninth Circuit authority. Nor does Plaintiff dispute that the first element of the *Riegel* test is satisfied here: through the PMA process, the federal government has established "requirements" applicable to the CI512 device. Plaintiff instead argues that his claims are based on state law duties that "parallel" federal law duties and therefore are not preempted.

The Court finds that Plaintiff has failed to provide sufficient factual detail to plead parallel state claims, and thereby avoid preemption, for all claims other than his

allegation that Defendants failed to warn the FDA. The Court will address the various categories of Plaintiff's claims individually.

A. Defective Manufacturing.

An introductory section of Plaintiff's complaint specifically states that he is pleading only parallel state law claims. Doc. 1, ¶¶ 9-15. The complaint attempts to do so by alleging that his state tort claims are premised solely on Defendants' failure to comply with the PMA and other federal requirements. Plaintiff alleges, for example, that "Defendants' manufacture of Plaintiff's Cochlear Implant deviated in a material way from the PMA, CGMP, Defendants' approved product specifications, approved manufacturing performance standards and/or other applicable federal law and federal regulations[.]" Doc. 1, ¶ 118. The complaint lists 30 PMA or federal standards Defendants purportedly failed to follow. *Id.* ¶ 114. These allegations – such as "Failed to comply with the MIL-STD-883 Test Method 2009 and/or JEDEC Standard 9 in the manufacture of the Cochlear Implant" – include no factual explanation of the failure. Plaintiff further alleges that Defendants' conduct "rendered the [CI512] defective, adulterated, and more dangerous than a reasonably prudent consumer would expect[.]" *Id.*, ¶ 119.

Although these allegations attempt to follow the form of parallel state claims, they are wholly conclusory. They include virtually no facts. Plaintiff therefore has failed to plead claims that are not preempted. As numerous cases have recognized, "Plaintiffs cannot simply incant the magic words '[Defendants] violated FDA regulations' in order to avoid preemption." *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009). "Parallel claims must be specifically stated in the initial pleadings." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). "To properly allege parallel claims, the complaint must set forth facts" pointing to specific PMA requirements that have been violated. *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). An allegation that "the manufacturing processes for the device . . . did not satisfy the [PMA] standards" is insufficient to plead a parallel claim if it fails to

"provide any factual detail to substantiate that crucial allegation." *Id.* at 1302; *see also Williamson v. Medtronic, Inc.*, No. 2:13-CV-02433, 2014 WL 2042004, at *7 (W.D. La., May 15, 2014) ("Mere assertions that a defendant is liable because a given product deviated from federal specifications and regulations without any more specificity are precisely the types of legal conclusions of which Rule 12(b)(6) motions are designed to dispose."); *Kashani-Matts*, 2014 WL 819392 at *3 ("Simply adding the 'magic words' that the device deviated from FDA-approved labeling and design, without any factual support, is not sufficient to save Plaintiff's claims from preemption."); *Hawkins*, 2014 WL 346622 at * 5 ("To properly plead parallel claims that survive preemption, a plaintiff must allege *facts* (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation.") (emphasis added); *Houston*, 2013 WL 3927839 at *5 (same); *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (same); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir.2010) ("Absent concrete allegations that the product sold by [defendant] was not the product design approved in the PMA Supplement, these are not parallel claims.").

B. Defective Design.

Plaintiff's design defect allegations suffer from the same shortcoming. The complaint alleges that the CI512 he received was "defective in design or formulation" and was "more dangerous than an ordinary consumer would expect because it failed to comply with federal requirements for such medical devices[.]" Doc. 1, ¶ 125. Plaintiff contends that the "unexpected variations in the brazing process violated the PMA's requirements, federal law and rendered the design of Plaintiff's Cochlear Implant to be *something other than the design approved by the FDA*." Doc. 40 at 13 (emphasis in original). As discussed above, Plaintiff must do more than simply state that Defendants' design violated federal law. Plaintiff has not pled facts supporting the allegation that the design of his CI512 was different than that approved in the PMA.

C. Failure to Warn.

Plaintiff contends that "Defendants violated a state law duty of care by failing to report known risks . . . to the FDA." Doc. 1, ¶ 130. He alleges that "Defendants failed to adequately warn healthcare professionals and the public, including Plaintiff and his physician, of the true risks of Plaintiff's Cochlear Implant[.]" *Id.*, ¶ 131. Plaintiff also alleges that Defendants failed to report to the FDA that the CI512 may have "caused or contributed to a serious injury or malfunctioned and that any recurring malfunction would be likely to cause or contribute to death or serious injury" in violation of 21 C.F.R. § 803.50(a) and 21 U.S.C. § 360i(a). *Id.*, ¶¶ 102, 114.

Plaintiff's claim that Defendants failed to warn healthcare professionals and the public is clearly preempted. Such a duty to warn is not imposed by federal law, and the state law claim would therefore impose a duty different from or in addition to those imposed by the FDCA, contrary to the preemption provision in § 360k. *See Stengel*, 705 F.3d at 1234 (Watford, J., concurring, joined by six judges) ("[A]ny attempt to predicate the [claim] on an alleged state law duty to warn doctors directly would have been expressly preempted under [§ 360k][.]"); *see also Kashani-Matts*, 2013 WL 6147032, at *4 ("[R]equiring warnings to doctors would be in addition to FDA requirements and thus expressly preempted by the MDA.").

Plaintiff's claim that Defendants failed to warn the FDA is not preempted. In *Stengel*, the Ninth Circuit specifically held that an Arizona-law claim for failure to warn the FDA is not preempted. 704 F.3d at 1233. Plaintiff provides little factual detail concerning the alleged failure to warn, but little factual detail is necessary or available when a plaintiff is alleging that the defendant failed to act. It is the absence of action that gives rise to the claim. The Court finds Plaintiff's failure-to-warn-the-FDA claim to be sufficiently pled to defeat preemption.[1]

[1] As Judge Watford noted, however, this claim could have difficulty at the causation stage because Plaintiff must show that had Defendants timely notified the FDA, the FDA would have passed the information along to Plaintiff's doctor in time to prevent his harm, and Plaintiff's doctor would have timely heeded the FDA warning. *Stengel*, 705 F.3d at 1234 (Watford, J., concurring, joined by six judges).

D. Negligence and Negligence Per Se.

Plaintiff alleges that Defendants "failed to exercise ordinary care in following the PMA, CGMP, federal law, and federal regulations in the design, formulation, testing, quality, assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of Plaintiff's Cochlear Implant[.]" Doc. 1, ¶ 137. Plaintiff also makes several allegations that Defendants "had a duty to warn Plaintiff or his physician of the dangers associated with the Cochlear Implant resulting from Defendants' failure to comply with" federal law and federal regulations. *Id.*, ¶¶ 139-40. Plaintiff argues that he has identified the "specific conduct that violated the duty" (Doc. 40 at 14), but the Court does not agree. As discussed above, Plaintiff's claim that Defendants failed to warn him or his doctor is expressly preempted, and Plaintiff's other negligence claims cannot simply put forth a laundry list of PMA or federal law provisions Defendants failed to follow without some factual allegations in support.

As to Plaintiff's negligence per se claim, Plaintiff alleges that Defendants breached their duty of ordinary care by introducing Plaintiff's CI512 into the stream of commerce when they knew it "had a propensity to fail and cause bodily harm and was not safe for use by consumers . . . because Defendants failed to comply with the PMA CGMP, federal law, or federal regulations." Doc. 1, ¶ 149. This claim lacks the same factual foundation as the allegations discussed above. Plaintiff provides no factual allegations regarding how Defendants failed to comply with the PMA and federal law. This claim also appears to be impliedly preempted because it is based directly on a violation of federal law. *Perez*, 711 F.3d at 1120; *see also Ramirez*, 961 F. Supp. 2d. at 1000 (finding the plaintiff's negligence per se claim impliedly preempted because it was "premised wholly on violations of the FDCA and the MDA").

E. Express and Implied Warranties.

Claims for breach of express and implied warranties are widely held to be preempted. *See, e.g., Kitchen v. Biomet, Inc.*, No. 13-18-HRW, 2014 WL 694226, at *6-7 (E.D. Ky., Feb. 21, 2014) ("[T]he representations a manufacturer may make with

respect to a PMA device are limited to those approved by the FDA, and express warranty claims are therefore preempted."); *Enlow v. St. Jude Medical, Inc.*, 210 F. Supp. 2d 853, 862 (W.D. Ky. 2001) (noting that implied warranty claims are "based on the accepted standards of design and manufacture of the products," which are set by the FDA "[i]n the case of a product that has gone through the PMA process," and concluding that "[a] state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it") (internal citation and quotation marks omitted); *see also Poll v. Stryker Sustainability Solutions, Inc.*, No. CIV 13-440-TUC-CKJ, 2014 WL 199150, at *6 (D. Ariz. Jan., 17, 2014) (warranty claims preempted). In addition, Plaintiff's briefing in support of the warranty claims cites law from outside this circuit that pre-dates *Riegel*. *See* Doc. 40 at 15.

F. Negligent Misrepresentation.

Plaintiff alleges that Defendants "negligently misrepresented to Plaintiff and/or Plaintiff's physicians that the Cochlear Implant's manufacture complied with the PMA CGMP, federal law and federal regulations," and that Plaintiff and his physicians relied on those representations. Doc. 1, ¶ 175. Plaintiff presents essentially no arguments in support of this claim, and Plaintiff's complaint pleads no facts to support the allegation that Defendants made any representations, let alone misrepresentations, to him or his doctors.

IV. Leave to Amend.

Plaintiff seeks leave to amend his complaint. Doc. 40 at 17. Rule 15 makes clear that the Court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). The Court will therefore grant Plaintiff's request for leave to amend.

IT IS ORDERED:

1. Defendants' motions to dismiss based on preemption (Docs. 26, 27) are granted in part and denied in as set forth above.

2. Plaintiff shall file an amended complaint on or before **August 15, 2014**.

3. This order does not dispose of the personal jurisdiction arguments set forth in Cochlear Limited's motion to dismiss. Doc. 27. The parties shall complete briefing on that motion under the schedule previously established by the Court.

Dated this 25th day of July, 2014.

David G. Campbell
United States District Judge